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PATENT & TRADEMARK OFFICE

Declaration under 37 C.F.R. § 1.132

I, Dr. Kirschbaum, declare and say:

1. I am a named inventor of the subject matter claimed in United States application serial no. 09/849,243 ("the Application").

2. I have received a Ph.D. in biology and have worked in the field of biochemistry/molecular biology for 17 years. My curriculum vitae is attached as Appendix A.

3. I understand that the claimed invention is directed to an epitope-tagged TBP transgenic animal, a method of making an epitope-tagged TBP transgenic animal, a method of expressing an epitope-tagged TBP in a transgenic animal, and a method for isolating a higher order transcription complex ("the claimed invention").

4. I have reviewed the Office Actions dated November 5, 1999, and November 7, 2000, and I understand that the Examiner questions whether the specification adequately teaches a skilled worker how to make and use the full scope of the claimed invention.

5. I further understand that the basis for the Examiner's position is that the Application allegedly does not teach a skilled worker how to make and/or use a transgenic animal of the type claimed, wherein the animal expresses the epitope-tagged TBP at a level sufficient to allow for the isolation of TBP-containing complexes.

6. In my professional opinion, however, the guidance set forth in the Application--coupled with the techniques available at the filing date of the Application--allows a skilled worker

in the field of molecular biology/biochemistry, through routine experimentation, to make and/or use such animals.

7. As objective evidence to support my statement in Paragraph 6, please find Examples 1-3 ("the Examples") appended hereto (Appendix B). The Examples show that I have been able to detect epitope-tagged TBP complex, differentiate such complex from endogenous murine TBP complex, and to isolate the associated TBP Associated Factors (TAFs), using the guidance set forth in the Application, in conjunction with the techniques available to a skilled worker in the field at the filing date of the Application.

8. I supervised another worker who performed the Examples.

9. All statements made hèrein of my knowledge are true and all statements made on information and belief are believed to be true; and further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or improsonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any document or any registration resulting therefrom.

B. Kirschbaum

Date:5.2.2002 Bernd Kirschbaum

APPENDIX B

Example 1: "Anti-TBP" Blots:

P11 purified nuclear extracts obtained from brain and from thymus of claimed transgenic mice were investigated.

In the left lane (P11 fraction, 0.9 M salt) endogenous mouse TBP complex and tagged TBP complex is detected. In lanes 3 and 5, the eluate obtained from the HA antibody column is analyzed, and only tagged TBP complex is detected. These results demonstrate that tagged TBP complex can be separated from endogenous murine TBP complex.

Example 2: "Anti TAF100 and Anti TAF30" Blot:

The same fractions as described in Example 1 were analyzed using anti TAF100 and anti TAF30 antibodies. Both TAF100 and TAF30 are detected in the P11 fraction and the affinity column eluate columns for brain and thymus. These results demonstrate that TBP was expressed in sufficient levels to allow the detection of TBP-containing complexes, and that the method is suitable to isolate the associated TAFs.

Example 3: "Anti TAF 135 and anti TAF55" Blot:

The same fractions as described in Example 1 were analyzed using anti TAF135 and anti TAF55 antibodies. TAF55 was detected in the P11 fraction and the affinity column eluate columns for brain and thymus. These results further demonstrate that TBP was expressed in sufficient levels to allow the detection of TBP-containing complexes.

CURRICULUM VITAE

Dr. Bernhard Kirschbaum
Date of birth: 25th of April 1958
Marital status: married, 2 children; Nationality: German

1964 - 1979	School education (A-level) and military service
	Study of Biology
1979 - 1984	Degree as 'Diplom-Biologe', 'excellent', University of Konstanz
	PhD work in Genetics, Biochemistry, Metabolism
1985 - 1989	PhD thesis: 'Coordination and dynamics of changes in myosin expression at the mRNA and protein levels in chronically stimulated skeletal muscle', 'summa cum laude', Prof. Dr. D. Pette, University of Konstanz
	Professional Experience
1989 - 1992	Postdoc with Prof. Dr. R. G. Roeder, The Rockefeller University, New York, N. Y., Laboratory of Biochemistry and Molecular Biology „Cloning and functional characterization of the OTF-2 promoter(s). Transcriptional regulation during B-cell differentiation", „Characterization of the activation domain(s) of the transcription factor USF"
1992 - 1993	Postdoc with Prof. Dr. M. Buckingham, Institut Pasteur, Paris „Functional interaction of the general transcription factor TFII-I with myogenic factors", „Characterization of the distal cardiac actin enhancer"
1993 – 1997	Hoechst AG, Wiesbaden, Head of research laboratory in the Disease Group Rheumatology
1997 - 1998	Hoechst Marion Roussel, Martinsried Acting head of The Center for Applied Genomics in Martinsried
since 1998	Frankfurt, Disease Group Head, HMR: Rheumatic/Autoimmune Diseases, Aventis: Thrombotic D. / Degenerative Joint D.
	Further Qualifications
Languages	German - native language; English - fluent; French - basic skills
Publications	25 scientific publications in international journals
Awards	Boehringer Ingelheim Scholarship 1985 – 1988 Postdoc-Scholarship, Deutschen Forschungsgemeinschaft 1989 – 1991 Lita Annenberg Hazen Scholarship, The Rockefeller University New York, 1991 – 1992 „Association Francaise contre les Myopathies Scholarship", 1992 Scholarship of the European Union 1993

Mainz, February 2002

Bernd Kirschbaum